

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Automated Function List § 1355.52(i)(2)	55	1	10	550
Data Quality Plan § 1355.52(d)(5)	55	1	40	2,200

Estimated Total Annual Burden Hours: 2,750.

Authority: 42 U.S.C. 620 *et seq.*, 42 U.S.C. 670 *et seq.*, 42 U.S.C. 1301 and 1302.

Mary B. Jones,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; Chronic Disease Self-Management Education Program; OMB #0985-0036

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

This notice solicits comments on the Proposed Revision and solicits comments on the information collection requirements related to ACL’s Chronic Disease Self-Management Education grant program.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by September 9, 2019.

ADDRESSES: Submit electronic comments on the collection of information to: Kristie Kulinski (*kristie.kulinski@acl.hhs.gov*). Submit written comments on the collection of information to Administration for Community Living, Washington, DC 20201, Attention: Kristie Kulinski.

FOR FURTHER INFORMATION CONTACT: Kristie Kulinski, Administration for Community Living, Washington, DC 20201, *kristie.kulinski@acl.hhs.gov* or (202) 795-7379.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

- (1) Whether the proposed collection of information is necessary for the proper performance of ACL’s functions, including whether the information will have practical utility;
- (2) the accuracy of ACL’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;
- (3) ways to enhance the quality, utility, and clarity of the information to be collected; and
- (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The “Empowering Older Adults and Adults with Disabilities through Chronic Disease Self-Management Education (CDSME) Programs” cooperative agreement program has

been financed through the Prevention and Public Health Fund (PPHF). The statutory authority for cooperative agreements under the most recent program announcement (FY 2019) is contained in the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Public Law 115-245; Public Health Service Act, 42 U.S.C. 300u-2 (Community Programs) and 300u-3 (Information Programs); and the Patient Protection and Affordable Care Act, 42 U.S.C. 300u-11 (Prevention and Public Health Fund). The Empowering Older Adults and Adults with Disabilities through CDSME Programs initiative supports a national resource center and awards competitive grants to deliver and sustain evidence-based CDSME interventions.

OMB approval of the existing set of data collection tools expires on October 31, 2019 (OMB Control Number 0985-0036). This data collection continues to be necessary for monitoring program operations and outcomes. ACL proposes to use the following tools: (1) Semi-annual program reports to monitor grantee progress; and (2) a set of tools used to collect information at each program completed by the program facilitators (Program Information Cover Sheet and Attendance Log) and a Participant Information Survey completed by each participant to document their demographic and health characteristics. ACL is not requesting renewal of Host/Implementation Organization Information Form. ACL intends to continue using an online data entry system for the program and participant survey data. In addition to non-substantive formatting edits, minor changes are being proposed to two of the four currently approved tools, as indicated below. All changes proposed are based on feedback from a focus group that included a sub-set of current grantees, as well as consultation with subject matter experts.

- Program Information Cover Sheet:
 1. Question #2: Added consent on behalf of the program facilitators to receive program updates/information from the National CDSME Resource Center.

2. Question #5: Additional evidence-based CDSME programs added to the list (reflective of approved programs included in the FY2019 Funding Opportunity Announcement).

3. Question #7: Information regarding funding source(s) requested to assess progress toward developing a sustainable program delivery infrastructure that is not solely reliant on ACL discretionary dollars.

- Participant Information Survey:

1. Participant I.D. modified to reduce risk of personally identifiable information exposure.

2. Question #10: Added question regarding veteran status to further describe program participants, as well

as to assist with partnerships with veteran-serving organizations.

3. Question #12: In tandem with Question #11, this item will allow for further assessment of caregiver status.

4. Question #14: Anxiety Disorder and Depression are listed separately (vs. being combined). Also included Yes/No response options for each chronic condition listed to improve data analyses and reporting.

5. Question #15: Response options have been delineated as sub-bullets (vs. being grouped into a single item) to align with the American Community Survey.

6. Question #16: Added question regarding social isolation, a construct

which has been demonstrated to have an association with health-related risks for older adults. This question will also be asked upon completion of the last program session.

7. Question #17: This question will be asked at baseline and upon completion of the last program session to measure change.

The proposed data collection tools may be found on the ACL website for review at <https://www.acl.gov/about-acl/public-input>.

Estimated Program Burden: ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Program facilitators (Program Information Cover Sheet, Attendance Log).	1,350	Once per program33	445.5
Program participants (Participant Information Survey)	13,500	120	2,700
Data entry staff (Program Information Cover Sheet, Attendance Log, Participant Information Survey).	65	Once per program times 1,350 programs.	.17	229.5
Total	3,375

Dated: June 27, 2019.

Mary Lazare,

Principal Deputy Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0595]

Advice About Eating Fish: For Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children, From the Environmental Protection Agency and Food and Drug Administration; Revised Fish Advice; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of revised fish advice entitled “Advice About Eating Fish: For Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children.” The revised advice updates advice that FDA and the U.S. Environmental Protection Agency (EPA) jointly issued in January 2017. The advice is intended to help women who are or might become pregnant, breastfeeding mothers, and parents of children over 2 years make

informed choices about fish that are nutritious and safe to eat. We are revising the advice in accordance with a recent directive from Congress. FDA is seeking public comment on the development of educational materials on the updated fish advice for women who are or might become pregnant, breastfeeding mothers, and parents of young children.

DATES: Although you can comment on the fish advice at any time, to ensure that FDA considers your comments on the development of educational materials before it begins work on such materials, submit either electronic or written comments on the requested information by September 9, 2019.

ADDRESSES: You may submit comments as follows.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:*

<https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or

confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2014-N-0595 for “Advice About Eating Fish: For Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children.” Received comments will be placed in the docket and, except for those submitted as “Confidential